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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/040,497	01/07/2002	Larry Gold	NEX05'DCC'ON2	3820

7590 04/08/2003

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EXAMINER

ZITOMER, STEPHANIE W

ART UNIT PAPER NUMBER

1634

DATE MAILED: 04/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/040,497

Applicant(s)

GOLD ET AL.

Examiner

Stephanie Zitomer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 January 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 1-07-02 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 1-07-02
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Rejections under 35 U.S.C. 112, second paragraph: Indefiniteness

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 1-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(a) Claims 1, 9, 15, 19, 28 and 33 are confusing because the claimed methods appear to be redundant in that all of them lead to the preparation or design of the same product. In each claimed method the product is "defined" by modifying a nucleic acid via adding, deleting or substituting nucleotide residues wherein the residues may be chemically modified and/or chemically modifying the nucleic acid ligand such that none of the methods generates a product that is distinct from the product of any other method. The recitation in claims 9, 15, 19, 28 and 33 that the recited modifications are "based on" a previously recited determination, such as the three-dimensional structure of the nucleic acid ligand, the residues responsible for target binding or the consensus sequence of multiple nucleic acid ligands, is indeterminate in that the modifications have no relationship to the "determination" on which they are putatively "based".

(b) Claims 4, 12, 18, 22, 31 and 36 are confusing in appearing to be redundant for the reasons given above (a) for the claims from which claims 4, 12, 18, 22, 31 and 36 depend. The "improved nucleic acid ligands" to which these claims are drawn lack distinguishing characteristics.

(c) In claims 1, 9, 28 and 33 the final "determining" step lacks antecedent basis in previous steps in that the "enhanced target function altering activity" should be compared not with the ligand *per se* but with its activity prior to improvement. For example, in claim 1 g), --the target function altering activity of-- should be inserted before "the nucleic acid ligand" and "step d)" should be --step e)--.

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(d) In claim 33, step e), "target modulatory activity" is *non sequitur* to "target function altering activity" elsewhere in the claim.

(e) Claim 39 is incomplete in omitting an essential step, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted step is determining the cell membrane permeability of the nucleic acid ligand identified in step d).

(f) In claim 39 the final "determining" step lacks antecedent basis in previous steps in that the "enhanced target function altering activity" should be compared not with the ligand *per se* but with its activity prior to improvement. See above at (c).

(g) Claim 39 is confusing due to the extraneous word "said" in e), line 2.

Prior art of interest

2. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Although not directly related to applicant's disclosure, the patent to Ladner et al. (5,223,409) is of interest in that it describes methods for preparing target binding proteins from mixed populations of variegated (semi-random and mutagenized) DNA and selecting the proteins by contacting with the target. The amino acid and corresponding nucleotide sequences of selected proteins may be determined for designing further variations of the binding proteins. Thus, the Ladner et al. method for preparing target binding proteins appears to parallel the SELEX method for preparing target binding nucleic acids.

Conclusion

3. **No claim is allowed.** However, the claims are free of the prior art and may be placed in condition for allowance by compliance with the requirements of 112, second paragraph, as set forth in the preceding rejection.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephanie Zitomer whose telephone number is (703) 308-3985. The examiner can normally be reached on Monday through Friday from 9:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152. The official fax phone number for this Group is

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(703) 308-4242. The unofficial fax number is (703) 308-8724. The examiner's Rightfax number is 703-746-3148.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196. For questions and requests relating to formal matters contact LIE Chantae Dessau at 703-605-1237.


Stephanie Zitomer, Ph.D.

April 7, 2003

STEPHANIE W. ZITOMER
PRIMARY EXAMINER